IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC.,)))
Plaintiffs,)
v.) C.A. No. 18-1869-CFC-CJB
MICRO-TECH ENDOSCOPY USA INC., MICRO-TECH (NANJING) CO., LTD., and HENRY SCHEIN INC.,)))
Defendants.)))

LETTER TO THE HONORABLE CHRISTOPHER J. BURKE REGARDING PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO STRIKE

Dated: January 20, 2021

Of Counsel:

Kevin M. Flannery Joseph J. Gribbin (DE Bar #5677) Daniel Roberts **DECHERT LLP** Cira Centre, 2929 Arch St. Philadelphia, PA 19104 (215) 994-2000

kevin.flannery@dechert.com joseph.gribbin@dechert.com daniel.roberts@dechert.com

Robert D. Rhoad **DECHERT LLP**502 Carnegie Center Drive, Suite #104

Princeton, New Jersey 08549
(609) 955-3200
robert.rhoad@dechert.com

Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
FARNAN LLP
919 North Market Street, 12th Floor
Wilmington, DE 19801
Tel. (302) 777-0300
Fax (302) 777-0301
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Plaintiffs

Dear Judge Burke:

Plaintiffs (collectively "BSC") respond to Defendants' letter motion to strike certain opinions of BSC's expert Karl Leinsing (D.I. 227) as follows:

Defendants fail to show that Mr. Leinsing's opinions were untimely, and in any event, with respect to every opinion Defendants seek to strike, they had an opportunity to depose Mr. Leinsing on his opinion and submit their own expert's reply opinion in response to it. Accordingly, Defendants fail to satisfy any of the five *Pennypack* factors¹ for excluding an expert's opinion.

For the first two *Pennypack* factors, there is no surprise or prejudice here, at a minimum because Mr. Leinsing's opinions were disclosed well before his deposition, which gave Defendants ample time to cure any alleged prejudice, and Defendants do not allege any prejudice in the taking of the deposition. Moreover, as discussed below, Defendants' experts had a full and fair opportunity to respond to Mr. Leinsing's opinions. See, e.g., Acceleration Bay LLC v. Activision Blizzard Inc., No. 16-cv-453-RGA, 2019 WL 4194060, at *7-8 (D. Del. Sept. 4, 2019). For the third *Pennypack* factor, Defendants have not identified how or why allowing Mr. Leinsing's opinions would disrupt to the trial schedule. They merely state, in conclusory fashion, that allowing Mr. Leinsing's opinions "would require the Court to abandon the current trial date and postpone summary judgment briefing" (D.I. 227 at 1), without explaining why either remedy would be required or justified. For the fourth *Pennypack* factor, Defendants cite no alleged misconduct other than stating without support that Mr. Leinsing's opinions "do not appear to have been disclosed in good faith" (D.I. 227 at 1)—and nothing near the clear, egregious examples of misconduct that Courts have required to satisfy this factor. See, e.g., Novartis Pharms. Corp. v. Actavis, Inc., No. 12-366-RGA-CJB, 2013 WL 7045056, at *11 (D. Del. Dec. 23, 2013). Finally, for the fifth Pennypack factor, Defendants assert hyperbolically that Mr. Leinsing's opinions with regard to "bushing" and "clip assembly" "alter the entire landscape of the infringement and invalidity issues for trial." D.I. 227 at 1. To the contrary, however, Defendants' infringement expert's report spanned 159 pages and 292 paragraphs, and he does not get to any "bushing" limitations until page 110, paragraph 191, and then spends only 13 paragraphs addressing them. See Ex. 1 (Plishka Rebuttal Report), ¶¶ 191-203. And he readily acknowledges that the accused devices have a "clip assembly." *Id.*, ¶¶ 71-76. Moreover, as shown below, Defendants' infringement expert did not even dispute Mr. Leinsing's opinion about these terms in his deposition, and Defendants' validity expert admitted at his deposition that he had a full and fair opportunity to reply to all of Mr. Leinsing's opinions on validity. In sum, all five *Pennypack* factors weigh against striking any of Mr. Leinsing's opinions.

A. Mr. Leinsing's Infringement Opinions Regarding the "Bushing" Limitations

Defendants' assertion that Mr. Leinsing's opinions regarding the "bushing" limitations depart from BSC's prior infringement contentions is based on a misreading of those contentions and an internal

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¹ The *Pennypack* factors are: (1) the prejudice or surprise to the moving party; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to disclose the testimony; and (5) the importance of the testimony sought to be excluded. *See Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977), overruled on other grounds by Goodman v. Lukens Steel Co., 777 F.2d 113 (3d Cir. 1985).

BSC document which Defendants falsely present as reflecting an infringement position that BSC previously took in this case. Mr. Leinsing's opinions regarding the "bushing" limitations were timely and there is no basis under the *Pennypack* factors to strike any of them.

1. '371 Patent Claim Element 1[d]

Defendants truncate the limitation at issue, which recites: "a bushing extending between a proximal end coupled to the sheath and a distal end releasably coupled to the capsule via a tab on the distal end of the bushing engaging the opening of the capsule." In his infringement report, Mr. Leinsing explains that the accused devices satisfy the above-italicized portion of the limitation because (1) they each include "spring tabs" which protrude out of holes in the distal end of the bushing and couple the bushing to the capsule by also extending through corresponding holes in the proximal end of the capsule, and (2) the bushing and capsule become uncoupled when the control wire is pulled far enough proximally to pull the prongs of the spring tabs out of the holes in the capsule, thereby freeing the capsule and clip from the remainder of the device, including the bushing. Defs. Ex. A, ¶¶ 146-147. And, as Mr. Leinsing explained in his reply report, his opinions are fully consistent with BSC's Final Infringement Contentions. Defs. Ex. C, ¶ 107.

Defendants try to parse the differences in wording between BSC's contentions and the way Mr. Leinsing expressed his opinions, but there is no requirement that an expert's opinions match a party's infringement contentions word-for-word,² and as Mr. Leinsing explained, the theory of infringement is the same—namely, that the accused devices satisfy this element by the combination of the distal end of the bushing and accompanying spring tabs, which together releasably couple the bushing to the capsule by engaging the opening of the capsule. Defs. Ex. C, ¶ 107. Nor was there a change in position between Mr. Leinsing's reports and his deposition, as Defendants also falsely assert. As Mr. Leinsing explained in Paragraph 108 of his reply report (Defs. Ex. C), the spring tabs are the claimed "tab on the distal end of the bushing" and satisfy that limitation because, as the device is manufactured and sold, they are "on" the distal end of the bushing notwithstanding the fact that they are not part of the bushing itself (just as a hat is "on" a person's head, even though it is not part of the person's head, or a glass of water is "on" a table, even though it is not part of the table).

The assertion of a doctrine of equivalents ("DOE") claim, as an alternative infringement theory, is also not new. BSC asserted it in its Final Infringement Contentions (Defs. Ex. D at 6), and Mr. Leinsing opined about it in both his opening and reply reports (Defs. Ex. A, ¶ 148; Defs. Ex. C, ¶ 113). Moreover, Defendants have not claimed, and cannot claim, any alleged surprise or uncurable prejudice arising out of any purported differences between the two that would justify striking Mr. Leinsing's opinions (*Pennypack* factors 1 and 2). Likewise, Defendants fail to show how or why these opinions would disrupt the trial schedule (*Pennypack* factor 3), nor do they point to any alleged bad faith or relative unimportance of the testimony that would weigh in favor of exclusion (*Pennypack* factors 4 and 5).

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² See, e.g., Acceleration Bay LLC v. Activision Blizzard LLC, No. 16-453-RGA, 2017 WL 11517421, at *3 (D. Del. Nov. 7, 2017) ("It is reasonable for expert reports to expand on, or amplify infringement contentions in reaching the expert's conclusions); see also Digital Reg of Tex., LLC v. Adobe Sys. Inc., No. 12-01971-CW-KAW, 2014 WL 1653131, at *5 (N.D. Cal. Apr. 24, 2014) ("That the expert report includes information outside of the infringement contentions, without altering the disclosed theory of infringement, is to be expected.").

2. '371 Claim 1, '725 Claims 2 and 3 – "Bushing"

Defendants' letter brief presents side-by-side, annotated pictures of portions of an accused device, as if they are a "before and after" representations of BSC's infringement positions showing a change over time. D.I. 227 at 3. However, they are not. Defendants cut and pasted the picture on the left from

See Ex. 2, slide 9. The document, which Defendants failed to attach to their motion, is not part of any infringement position BSC has taken in this case—it makes no mention of any patents, was not prepared in view of any patent claim or claim language, and was not part of or cited in any of BSC's infringement contentions or any of its expert's infringement reports.

With respect to the positions BSC has actually taken in this litigation, BSC has consistently asserted that the bushing is coupled to the distal end of the coil shaft (sometimes also referred to as a "wire coil"). As can be seen on the right-hand picture in Defendants' letter (though partially blocked by the yellow box that Defendants added), and is also shown in the pictures Mr. Leinsing included at ¶¶ 43-46 of his opening report (Defs. Ex. A), what BSC and Mr. Leinsing call the "bushing" is welded to the distal end of the wire coil that comprises the coil shaft of the accused devices. Thus, neither BSC nor Mr. Leinsing contends that the bushing is part of the coil shaft, as Defendants' falsely assert: it is welded to the distal end of it. Mr. Leinsing's opinions do not depart from any previous infringement position posited by BSC, and therefore, there is no surprise or prejudice to Defendants under *Pennypack* factor one. Of note, Defendants' non-infringement expert does not dispute that what Mr. Leinsing identifies as the "bushing" of the accused devices is, in fact, a bushing. Ex. 3 (Plishka Dep. Tr.) at 192:5-12. And again, Defendants fail to show how or why these opinions would disrupt the trial schedule (*Pennypack* factor 3), nor do they point to any alleged bad faith or relative unimportance of the testimony that would weigh in favor of exclusion (*Pennypack* factors 4 and 5).

Defendants point to Mr. Leinsing's reference to "clearance between the sheath and the bushing" in his opening report, but that has no bearing on this issue. Mr. Leinsing was referring to the fact that the bushing is composed of two parts, one of which is able to rotate in relation to the sheath, and explaining why, contrary to Defendants' non-infringement contentions, the bushing is not thereby excluded by the Court's construction of the phrase "coupled to the sheath" as meaning that the bushing is linked together, connected, or joined to the sheath, but not "slidable within the sheath." See Defs. Ex. A, ¶¶ 51, 150.3

B. Mr. Leinsing's Opinions Regarding the Clip Assembly

Defendants argue that Mr. Leinsing's reply report "attempts to exclude the 'internal counterbores' from being part of the clip assembly in a footnote." D.I. 227 at 3. The Court construed the term "clip assembly" to mean "an assembly having a clip ..."—that is, a clip plus one or more additional components. See D.I. 140 at 2. In his opening report, Mr. Leinsing included the internal counterbores of the capsule as one of several components of the accused devices that can be

105. Thus, there is no basis to strike those paragraphs in any event.

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³ Even if the bushing were somehow limited to just the part thereof that is able to rotate in relation to the sheath, which seems to be Defendants' position (and one which BSC disputes), the relief Defendants seek is overbroad. As Mr. Leinsing explained in his reply report, the accused devices would still meet the "bushing" limitations under such an interpretation. *See* Defs. Ex. C, ¶¶ 103-

considered part of the "clip assembly." Defs. Ex. A at ¶ 140. However, Defendants' expert questioned the inclusion of the internal counterbores. In response thereto, Mr. Leinsing explained in his reply report that the internal counterbores need not be included as part of the claimed "clip assembly" and that the accused devices infringe whether or not they are included. *See* Defs. Ex. C, ¶ 125 n. 9 ("excluding the internal counterbores from the clip assembly does not affect any [of] the analysis of infringement," and the accused devices infringe "regardless of whether the internal counterbores are included or excluded as part of the clip assembly"). Thus, Mr. Leinsing's opinions are a proper and timely reply to Defendants' rebuttal expert reports. Indeed, Defendants' non-infringement expert, Mr. Plishka, testified in his deposition that he had no opinion as to what would properly be considered to part of the "clip assembly" of the accused devices, and that he only responded to what Mr. Leinsing opined is the "clip assembly." Ex. 3 at 160:21-163:21.

Moreover, Defendants had a full opportunity to depose Mr. Leinsing on this issue over two full days and they reserved no rights on this issue—or any other issue—during the deposition. Accordingly, there is no prejudice to Defendants that would justify striking Mr. Leinsing's opinion. And yet again, Defendants fail to show how or why these opinions would disrupt the trial schedule (*Pennypack* factor 3), nor do they point to any alleged bad faith or relative unimportance of the testimony that would weigh in favor of exclusion (*Pennypack* factors 4 and 5).

C. Mr. Leinsing's Rebuttal Validity Report

Defendants seek to strike portions of Mr. Leinsing's rebuttal to Defendants' invalidity expert report relating to specified prior art references (Sugiyama, Kimura and Kortenbach I) and particular claims of the '725 patent as "untimely." D.I. 227 at 4. Their argument has no merit.

In their Amended Initial Invalidity Contentions, Defendants did not include an invalidity claim chart for Kortenbach I with respect to the '725 patent (though they did for the '245 and '371 patents), and the '725 invalidity claim charts for Sugiyama and Kimura were woefully deficient the charts included repeated citations to the same or similar groups of paragraphs and figures as allegedly disclosing each claim element, without any explanation of which component(s) of any devices disclosed in the reference correspond to any claim limitation. See Ex. 4 (Amended Initial Invalidity Contentions) at 19-20, Exhibits B1, B3. On April 7, 2020, BSC wrote to Defendants complaining about these and other deficiencies in Defendants' Amended Invalidity Contentions. Ex. 5. Defendants never responded or did anything to correct the deficiencies. Defendants' Interrogatory No. 11 asked BSC to describe its contentions that the asserted patent claims are "not invalid as Defendants contend in their Amended Initial Invalidity Contentions." Defs. Ex. I at 2. In its responses thereto, BSC reiterated that the insufficient disclosures in Defendants' contentions did not fairly disclose their position as to how the cited prior art disclosed the claimed inventions, but nonetheless endeavored to respond the best it could and reserved its rights to, among other things, respond in more detail in its rebuttal expert reports. Defs. Ex. I at 10-11, 19-20, 21-22. Defendants served their Final Invalidity Contentions on August 31, 2020, just 11 days before the close of fact discovery. Those contentions added numerous additional disclosures and dozens of new invalidity arguments and theories to this case (including, for instance, adding Kortenbach I as allegedly anticipatory art to the '725 patent). There was insufficient time for BSC to adequately respond to any new information in those Final Contentions within the few days left for fact discovery, but more importantly, Defendants' interrogatory was limited, by its own terms, to BSC's responses to their Amended Invalidity Contentions and BSC had already fully responded to that Interrogatory without any objection by Defendants. Nevertheless, although it was under no obligation to do so, BSC provided some supplemental validity contentions prior to the close of fact discovery, while reserving its right to further respond in its rebuttal expert reports (again, with no objection from Defendants).

Thus, the specified portions of Mr. Leinsing's rebuttal validity report are neither untimely nor improper. Any alleged inadequacy in BSC's responsive validity contentions are attributable to the deficiencies in Defendants' Amended Initial Invalidity Contentions and the withholding of the disclosure of Defendants' true contentions until the eve of the fact-discovery cutoff. *See* D.I. 29 § 8(d)(ii) ("The adequacy of all interrogatory answers shall, in part, be judged by the level of detail each party provides; i.e., the more detail a party provides, the more detail a party shall receive."). Indeed, even if Defendants had served an interrogatory seeking BSC's responses to their Final Invalidity Contentions, BSC could not have been expected to fully address all of the new disclosures and invalidity arguments raised in those contentions in the 11 days before fact discovery closed.

Moreover, Defendants bear the burden of proving invalidity, and they do not and cannot claim any undue prejudice as a result of any allegedly untimely disclosure. To the contrary, at his deposition, Defendants' invalidity expert admitted that "I had [Mr. Leinsing's] report so I feel like I had an opportunity to respond." Ex. 6 (Jensen Dep. Tr.) at 25:24-26:3. The Court should decide this case based on the merits, not on the basis of Defendants' "gotcha" arguments designed to avoid those merits. Nor have Defendants shown how or why these opinions would disrupt the trial schedule (*Pennypack* factor 3), nor any alleged bad faith or relative unimportance of the testimony that would weigh in favor of exclusion (*Pennypack* factors 4 and 5).

D. Priority Date for the '245 Patent

The issue presented—whether the Kimura reference qualifies as prior art to the '245 patent based on the date of its inventor's oath rather than its filing date—is a purely legal one that is not properly the subject of expert testimony, by either side's experts. In fact, BSC intends to raise this issue by way of summary judgment. Thus, although Plaintiffs vigorously dispute Defendants' assertions that they reneged on any agreement and the substance of Defendants' assertions regarding this issue, and although Plaintiffs included opinions in Mr. Leinsing's report simply in response to Dr. Jensen's assertions regarding this legal issue, neither Mr. Leinsing's nor Dr. Jensen's statements have any relevance to the matter and Plaintiffs consent to withdrawal of the opinions set forth in Paragraphs 164-170 of Mr. Leinsing's rebuttal validity report, which are the ones to which Defendants object.

E. Mr. Leinsing's Opinions Regarding the Practicing Products

Defendants assert that Mr. Leinsing's opinions that the asserted patent claims cover BSC's Resolution and Resolution 360 Clips are untimely. This assertion misconstrues both the applicable legal standards and the facts and circumstances presented here. Moreover, as with the other issues here, Defendants do not even allege specific prejudice or attempt to justify the extreme sanction of excluding an expert's opinions.

First, Defendants falsely assert that "Plaintiffs did not provide any opinion or analysis by Mr. Leinsing, or any other expert, in an opening report" about whether the Resolution and Resolution 360 clips practice the asserted claims. In fact, Mr. Leinsing opined in his opening report that "[t]he elements of the Resolution and Resolution 360 clip design are fully described in the specifications

of the '245, '371, and '725 patents, and both products are covered by the asserted claims of the '245, '371, and '725 patents." Defs. Ex. A \P 39.

Second, it is well-established that a patentee need not prove that its products are covered by the asserted patents in order to recover lost profits. *See, e.g., Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1380 (Fed. Cir. 2017) ("A patentee can recover lost profits even if its product does not practice the claimed invention, where the product directly competes with the infringing device."). As the Federal Circuit has made clear, direct competition is all that is required, and that is the analysis that BSC's damages expert (Mr. Bone) provided. Thus, BSC was under no obligation to prove in its opening reports that the Resolution and Resolution 360 devices embody the claims of the asserted patents, even though Mr. Leinsing opined that they do.

Moreover, in further support of his lost-profits damages opinions, Mr. Bone pointed to BSC's interrogatory responses demonstrating that the Resolution and Resolution 360 practice the asserted claims. Ex. 7 (Bone Opening Report) ¶ 161. Defendants never contended during discovery that the Resolution and Resolution 360 did not practice the asserted claims, and none of their experts affirmatively do so now. In fact, in their Final Invalidity Contentions, Defendants acknowledged BSC's assertions that its clips embody the asserted patents, and they expressly admitted that at least the Resolution Clip does practice the '371 and '725 patents. See Ex. 8 (Final Invalidity Contentions) at 7, 49, 63 ("Plaintiffs further admit that testing of the Resolution Clip, which practices the '725 and '371 claims, when compared to the prior art Olympus Endoclips...") (emphasis added).

Defendants first raised an issue regarding the Resolution and Resolution 360 clips practicing the asserted patents in the opening invalidity expert report of Dr. Jensen, who opined that nexus should not be presumed for purposes of secondary considerations "because Plaintiffs have not alleged that their Resolution clip devices practice the Asserted Claims under the Court's claim construction order." Ex. 9 (Jensen Opening Report), ¶ 546. BSC responded to this newly raised argument as part of the secondary considerations opinions in Mr. Leinsing's rebuttal validity report, where they properly belong, including claim charts mapping the exemplary Resolution 360 products to the asserted claims. There was no reason for Mr. Leinsing to include these charts in his opening infringement report, as it was not part of BSC's affirmative case, and his opinions were presented in rebuttal to the arguments that Dr. Jensen made in his opening report.

Defendants now argue that it is too late for them to respond. D.I. 227 at 4. That is also false. The schedule allowed reply expert reports, so Defendants' experts had an opportunity to include any response to Mr. Leinsing's opinions and claim charts in a reply report. Whether Mr. Leinsing presented those opinions and claim charts in the opening or rebuttal report phase, Defendants and their experts had a full and fair opportunity to respond as they wished. They cannot show that there was any surprise or that they suffered any alleged prejudice. And, although Defendants fail to acknowledge it in their letter, Dr. Jensen actually did respond in his reply report. See Ex. 10 (Jensen Reply Report) ¶¶ 165-175. At his deposition, Dr. Jensen responded to substantive questions on these issues, and acknowledged that he had a full and fair opportunity to respond to everything in Mr. Leinsing's rebuttal report. Ex. 6 at 25:24-26:3, 28:14-34:7. Thus, not only is there no basis to contend that Mr. Leinsing's opinions were untimely, there is also no basis for Defendants to claim that they have suffered any prejudice or that any of the other Pennypack factors would weigh in favor of striking those opinions.

Respectfully submitted,

/s/ Brian E. Farnan

Brian E. Farnan

cc: Counsel of Record (Via E-Mail)